

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

*IFW*

Applicants: Thomas M. DiMauro, Mohamed Attawia, Hassan Serhan, Martin A. Reynolds,  
Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder,  
Gregory Collins, Laura J. Brown, Jeffrey Geesin, Pamela L. Plouhar,  
Catherine W. Smith and John Siekierka

Application No.: 10/630,227

Group Art Unit: 1647

Filed: July 30, 2003

Examiner: Lee, Betty L.

Confirmation No.: 8291

Title: TRANS-CAPSULAR ADMINISTRATION OF HIGH SPECIFICITY  
CYTOKINE INHIBITORS INTO ORTHOPEDIC JOINTS

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
10-11-05	<i>Jennifer Torpey</i>
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Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references, B1-B14 and C1-C38, are enclosed.
- ☐ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☒ The listed references, A17-A20, B9, B11-B14, C37 and C38, were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - ☐ the enclosed English language abstract.

[ X ] Applicant requests that the following pending applications be considered:

Examiner's  
Initials

- U.S. Patent Application No. 10/456,948, by Thomas M. DiMauro, Hassan Serhan, Mohamed Attawia, Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder, Gregory Collins and John Siekierka, filed June 6, 2003, Docket No.: 3518.1012-001.
- U.S. Patent Application No. 10/610,355, by Hassan Serhan, Thomas M. DiMauro, Mohamed Attawia, Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder and Gregory Collins, filed June 30, 2003, Docket No.: 3518.1012-002.
- U.S. Patent Application No. 10/631,487, by Thomas M. DiMauro, Hassan Serhan,, Mohamed Attawia, Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder, Gregory Collins, Laura J. Brown, Jeff Geesin, Pam Plouhar, Catherine Smith and John Siekierka, filed July 31, 2003, Docket No.: 3518.1012-003.
- U.S. Patent Application No. 10/714,594, by Mohamed Attawia, Hassan Serhan, Thomas M. DiMauro, Melissa Grace and David Urbahns, filed November 14, 2003, Docket No.: 3518.1012-005.
- U.S. Patent Application No. 10/640,412, by Mohamed Attawia, Thomas M. DiMauro, Hassan Serhan, Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder, Gregory Collins, Laura J. Brown, Jeff Geesin, Pamela L. Plouhar, Catherine Smith and John Siekierka, filed August 13, 2003, Docket No.: 3518.1019-000.
- U.S. Patent Application No. 10/723,250, by Thomas M. DiMauro, Mohamed Attawia, Hassan Serhan, Melissa Grace, Michael Slivka, Thomas G. Ferro, Vivek N. Shenoy, Alonzo D. Cook, and Scott Bruder, filed November 26, 2003, Docket No.: 3518.1024-000.

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Examiner

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Date

- [ X ] A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- [ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

## Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[      ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: October 11, 2005

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
3518.1015-000APPLICATION NO.  
10/630,227INFORMATION DISCLOSURE CITATION  
IN AN APPLICATIONFIRST NAMED INVENTOR  
Thomas M. DiMauroFILING DATE  
July 30, 2003

October 11, 2005

(Use several sheets if necessary)

EXAMINER  
Lee, Betty L.CONFIRMATION NO.  
8291GROUP  
1647

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A1	2003/0039651 A1	02-27-2003	Olmarker
	A2	6,419,944 B2	07-16-2002	Tobinick
	A3	2003/0049256 A1	03-13-2003	Tobinick
	A4	2002/0026244 A1	02-28-2002	Trieu
	A5	5,095,037	03-10-1992	Iwamitsu <i>et al.</i>
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	A8	6,284,471 B1	09-04-2001	Le <i>et al.</i>
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	A13	6,541,477 B2	04-01-2003	Goehring <i>et al.</i>
	A14	5,965,583	10-12-1999	Beers <i>et al.</i>
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	A16	5,270,300	12-14-1993	Hunziker
	A17	6,294,170 B1	09-25-2001	Boone <i>et al.</i>
	A18	2001/0016195 A1	08-23-2001	Tobinick
	A19	5,368,841	11-29-1994	Trauner <i>et al.</i>
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	A21	5,656,272	08-12-1997	Le <i>et al.</i>

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>October 11, 2005</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. <b>3518.1015-000</b>		APPLICATION NO. <b>10/630,227</b>	
	FIRST NAMED INVENTOR <b>Thomas M. DiMauro</b>		FILING DATE <b>July 30, 2003</b>	
	EXAMINER <b>Lee, Betty L.</b>		CONFIRMATION NO. <b>8291</b>	GROUP <b>1647</b>

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	B1	EP 1153607 A2	11-14-2001	Dunn		
	B2	WO 03/000190 A2	01-03-2003	DePuy		
	B3	WO 02/057240 A1	07-25-2002	Ortho Mc Neil Pharmaceutical, Inc.		
	B4	WO 91/02078	02-21-1991	Peptide Technology LTD		
	B5	EP 0 218 868 A2	04-22-1987	New York Blood Center, Inc.		
	B6	EP 0 288 088 B1	10-26-1988	Teijin Limited		
	B7	WO 92/07076	04-30-1992	The Charing Cross Sunley Research Centre		
	B8	WO 2004/022078 A1	03-18-2004	The Royal Veterinary College		
	B9	WO 97/28828	08-14-1997	Amgen Boulder Inc.		
	B10	WO 92/16553	10-01-1992	New York University		
	B11	WO 98/24477	06-11-1998	Amgen Inc.		
	B12	EP 1 133 995 A2	09-19-2001	Synergen, Inc.		
	B13	WO 01/85179 A2	11-15-2001	Clemson University		
	B14	EP 0 438 234 A1	07-24-1991	Kita		

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	EXAMINER Lee, Betty L.	CONFIRMATION NO. 8291	GROUP 1647	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C1	Braun, J. and Sieper J., "Overview of The Use of The Anti-TNF Agent Infliximab in Chronic Inflammatory Diseases," <i>Expert Opin. Biol. Ther.</i> 3(1):141-168 (2003).	
C2	Braun, J., <i>et al.</i> , "Anti-Tumour Necrosis Factor $\alpha$ Therapy for Ankylosing Spondylitis: International Experience," <i>Ann. Rheum. Dis.</i> , 61(Supp. III):iii51-iii60 (2002).	
C3	Olmarker, K. and Rydevik, B., "Selective Inhibition of Tumor Necrosis Factor- $\alpha$ Prevents Nucleus Pulposus-Induced Thrombus Formation, Intraneural Edema, and Reduction of Nerve Conduction Velocity," <i>Spine</i> , 26(8):863-869 (2001).	
C4	Aoki, Y., <i>et al.</i> , "Local Application of Disc-Related Cytokines on Spinal Nerve Roots," <i>Spine</i> 27(15): 1614-1617 (2002).	
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C7	Igarashi <i>et al.</i> , Inflammatory Cytokines From Facet Joint Tissue in Degenerative Lumbar Disorder, ISSLS Abstract #262 (May 13-17, 2003).	
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C9	Kawakami, M. <i>et al.</i> , "Possible Mechanism of Painful Radiculopathy in Lumbar Disc Herniation," <i>Clin. Orthop.</i> 351:241-251(1998).	
C10	Gordon, J.L., <i>et al.</i> , "Metalloproteinase Inhibitors as Therapeutics," <i>Clin. Exp. Rheumatol.</i> , 11(Supp 8): S91-S94 (1993).	
C11	Johnson, W.H., <i>et al.</i> , "Collagenase Inhibitors: Their Design and Potential Therapeutic Use," <i>J. Enzyme Inhib.</i> , 2:1-22 (1987).	
C12	Möller, A. <i>et al.</i> , "Monoclonal Antibodies to Human Tumor Necrosis Factor $\alpha$ : In Vitro and In Vivo Application," <i>Cytokine</i> 2(3):162-169 (1990).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C13		Liang, C.-M., <i>et al.</i> , "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," <i>Biochem. Biophys. Res. Comm.</i> 137:847-854 (1986).
C14		Meager, A., <i>et al.</i> , "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," <i>Hybridoma</i> 6(3):305-311 (1987).
C15		Fendly <i>et al.</i> , "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," <i>Hybridoma</i> 6:359-370 (1987).
C16		Bringman, T.S., <i>et al.</i> , "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> 6(5):489-507 (1987).
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C19		Loetscher, H., <i>et al.</i> , "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," <i>Cell</i> , 61:351-359 (1990).
C20		Corcoran, A., <i>et al.</i> , "Characterization of Ligand Binding by the Human p55 Tumour-Necrosis-Factor Receptor," <i>Eur. J. Biochem.</i> , 223:831-840 (1994).
C21		Engelmann, H. <i>et al.</i> , "Two Tumor Necrosis Factor-Binding Proteins Purified From Human Urine," <i>J. Biol. Chem.</i> , 265(3):1531-1536 (1990).
C22		Lesslauer, W., <i>et al.</i> , "Recombinant Soluble Tumor Necrosis Factor Receptor Proteins Protect Mice from Lipopolysaccharide-Induced Lethality," <i>Eur. J. Immunol.</i> , 21:2883-2886 (1991).
C23		Ashkenazi, A., <i>et al.</i> , "Protection Against Endotoxic Shock by a Tumor Necrosis Factor Receptor Immunoadhesin," <i>Proc. Natl. Acad. Sci. USA</i> 88:10535-10539 (1991).
C24		Peppel, K., <i>et al.</i> , "A Tumor Necrosis Factor (TNF) Receptor-IgG Heavy Chain Chimeric Protein as a Bivalent Antagonist of TNF Activity," <i>J. Exp. Med.</i> , 174:1483-1489 (1991).
EXAMINER		DATE CONSIDERED



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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C25	Capon, D., <i>et al.</i> , "Designing CD4 Immunoadhesins for AIDS Therapy," <i>Nature</i> , 337:525-531 (1989).	
C26	Kolls, J., <i>et al.</i> , "Prolonged and Effective Blockade of Tumor Necrosis Factor Activity Through Adenovirus-Mediated Gene Transfer," <i>Proc. Natl. Acad. Sci. USA</i> 91:215-219 (1994).	
C27	Butler, D., <i>et al.</i> , "TNF Receptor Fusion Proteins are Effective Inhibitors of TNF-Mediated Cytotoxicity on Human KYM-1D4 Rhabdomyosarcoma Cells," <i>Cytokine</i> , 6(6):616-623 (1994).	
C28	Baker, D., <i>et al.</i> , "Control of Established Experimental Allergic Encephalomyelitis by Inhibition of Tumor Necrosis Factor (TNF) Activity within the Central Nervous System using Monoclonal Antibodies and TNF Receptor-Immunoglobulin Fusion Proteins," <i>Eur. J. Immunol.</i> , 24:2040-2048 (1994).	
C29	Zhang, C., <i>et al.</i> , "Mitogen-activated Protein (MAP) Kinase Regulates Production of Tumor Necrosis Factor- $\alpha$ and Release of Arachidonic Acid in Mast Cells," <i>J. Biol. Chem.</i> , 272(20): 13397-13402 (1997).	
C30	Pargellis, C., <i>et al.</i> , "Inhibition of p38 MAP Kinase by Utilizing a Novel Allosteric Binding Site," <i>Nature Structural Biology</i> , 9(4): 268-272 (2002).	
C31	Chae, H.J., <i>et al.</i> , "The p38 Mitogen-activated Protein Kinase Pathway Regulates Interleukin-6 Synthesis in Response to Tumor Necrosis Factor in Osteoblasts," <i>Bone</i> , 28(1): 45-53 (2001).	
C32	Cirillo, P., <i>et al.</i> , "The Non-Diaryl Heterocycle Classes of p38 MAP Kinase Inhibitors," <i>Current Topics in Medicinal Chemistry</i> , 2:1021-1035 (2002).	
C33	Boehm, J. and Adams, J., "New Inhibitors of p38 Kinase," <i>Exp. Opin. Ther. Patents</i> , 10(1):25-38 (2000).	
C34	Lee <i>et al.</i> , "Inhibition of p38 MAP Kinase as a Therapeutic Strategy," <i>Immunopharmacology</i> , 47:185-2001 (2000).	
C35	Brown, K., <i>et al.</i> , "Gelatin/Chondroitin 6-Sulfate Microspheres for the Delivery of Therapeutic Proteins to the Joint," <i>Arthritis. Rheum.</i> , 41(12):2185-2195 (1998).	
C36	Burke, J.G., <i>et al.</i> , "Intervertebral Discs Which Cause Low Back Pain Secrete High Levels of Proinflammatory Mediators," <i>JBJS</i> , 84-B(2):196-201 (2002).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C37	Gabay, C., "IL-1 Trap," <i>Curr. Opin. Invest. Drugs, Curr. Drugs</i> , London, GB, 4(5):593-597 (2003).	
C38	Dayer, J.M., "The Pivotal Role of Interleukin-1 in the Clinical Manifestations of Rheumatoid Arthritis," <i>Rheumatology, Oxford Univeristy Press</i> , London, GB, 42(Suppl 2):ii03-ii10 (2003).	

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